DRUG USE REVIEW (DUR) BOARD

Board Approved Minutes
January 27, 2011

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV 89119

Magellan Medicaid Administration
885 Trademark Dr., Suite 150
Reno, NV 89521

Committee Members Present:
Las Vegas: Paul Oesterman, Pharm.D., James Marx, MD,
Reno: David England, Pharm.D, Keith Macdonald, R.Ph., Chris Shea, Pharm.D
Absent: William Evans, MD; Steven Rubin, MD;

Others Present:
DHCFP:
Las Vegas: Gabriel Lither; Deputy Attorney General
Reno: Coleen Lawrence, Chief, Program Services; Jennifer Matus, Pharmacy Program Specialist

Magellan Medicaid Administration:
Las Vegas: Paula Townsend Pharm.D; Clinical Manager; Rob Coppola Pharm.D., Program Director; Shirley Hunting
Reno: Judy LaFleur

Others
Las Vegas: Steve Nelson-Merck; Chris Almedia-Purdue; Susan Wood-Boehringer Ingelheim; Brooks Hubbard-Boehringer Ingelheim; Sandy Sierawski-Pfizer; Bret Ferguson-Pfizer; David Huffaker-University of Southern Nevada; Doug Powell-Forest; Jim Elowitt-Forest; Rajiv Dass-Sunovion; Dane Hallberg-Sunovion; Jeff Scheneman-Pfizer; Bret Brewer-EMD Serono
Reno: Julie Bertuleit-GSK; Larry Ashton-Integricare

i. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 1:02 p.m.

ii. Discussion and Approval of October 28, 2010 Minutes

MOTION: James Marx motioned to accept the October 28, 2010, minutes as presented.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

Dr. Oesterman referred to the October 28, 2010, meeting minutes noting that page 2, second paragraph states that "pharmacists have prescriptive authority for prescribing over-the-counter and legend tobacco cessation products will be agendized on a future agenda." He requested this item be placed on the agenda for the next meeting. In addition, the recommendation on page 8 of the minutes regarding PPIs included a request for "additional cost data and step-therapy recommendations be presented at the next meeting." This was not on today's agenda and Dr. Oesterman requested it be agendized for the next meeting.

iii. Status Update by DHCFP

a. Program Updates

Coleen Lawrence stated that DHCFP is currently preparing for the upcoming legislative session. The State budget will be addressed during this session; the Medicaid budget is typically one of the final budgets to close which will be at the end of May.

In January, 2011, the Board of Examiners signed an agreement for a new State MMIS contractor which also included the pharmacy program. The new contractor, Hewlett Packard (HP) will replace Magellan Medicaid Administration. Because the take over will be in progress during the next quarterly DUR Board meeting, the agenda will be light. DHCFP is reformatting Chapter 1200, Prescribed Drugs of the Medicaid Service Manual, to be more user-friendly for pharmacists and physicians. It will include a quantity limitations pullout guide which will be presented at the next board meeting.

iv. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Dr. Townsend reported that antipsychotics continue to maintain the top position as indicated in the report ranked by payment amount. Total utilization for the fourth quarter has increased. The number of recipients receiving these drugs has increased by approximately 1,160 more recipients in the fourth quarter of 2010 versus the fourth quarter in 2009. Synagis® (W5D class) is back in the top ten due to the fall season, however, its 40% less than during the same timeframe last year, possibly due to the revised prior authorization criteria and implementation of the CDC recommended season for RSV vaccination. Analgesics and anticonvulsants continue to rank high in claims volume. Trends are consistent with other similar state plans.

The Board questioned the increase in utilization and decrease in cost; the disparity between the cost and payment in the analgesics which indicates a difference in cost of approximately two dollars per prescription and the muscle relaxants are substantially higher and asked if the decrease in payment in the analgesics and anticonvulsants is due to action by the DUR Board or has there been a major decrease in cost in the retail sector. Dr. Townsend replied that there have been no changes in the market or reimbursement that would have impacted this cost. Dr. Coppola added that it may be generic pricing related. The MAC pricing formula has not changed but there may be more manufacturers subject to the MAC price.

Dr. Oesterman requested a drug mix analysis of the narcotic analgesics and anticonvulsant classes be presented at the next meeting.

b. Top 50 Drugs (by Payment and by Claims)

A more detailed summary of the above reported information is available in the Top 50 Drugs report.

c. Program Trends

Dr. Townsend stated that total recipients continue to increase. In December, 2010, there were 85,941 recipients enrolled compared to 78,807 in December, 2009. Utilizing recipients remain consistent at approximately 40%. Total claims increased moderately from 111,866 in December, 2009, to 120,980 in December, 2010. Generic utilization continues to slowly increase and is currently at 76.4%.

v. Concurrent Drug Utilization Review (ProDUR)

a. Review of Q4 2010

Dr. Townsend reported that the number of alerts remain consistent with therapeutic duplication occupying the top position in the number of alerts sent to pharmacies; drug-to-age edits second; drug-

to-drug third. In terms of the drug-to-gender edit, she is in the process of obtaining access to a report that can provide detail on which drugs are hitting the edit.

Dr. Oesterman requested a report on drug-to-gender in both Severity Level 1 and 2 which breaks down the different products be provided to the Board at the next meeting.

vi. Retrospective Drug Utilization Review (RetroDUR)

a. Review of Responses

Dr. Townsend reviewed the RetroDUR Letter Response Report by Response Code for the third quarter of 2010. The provider response rate was high in July (22%-Non-compliance with antihypertensive agents) and August (18%-Tramadol with SSRIs or SNRIs) but declined in September (3%-Triptans interact w/SSRIs). A 15% response rate is the annual review average.

b. Status of Previous Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria and the number of profiles lettered for the third quarter of 2010.

c. Status of Current Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria for fourth quarter 2010, noting that this quarter is still in data collection mode. December profiles were generated this week for the criteria "non-compliance with SSRIs".

d. Public Comment

No comment.

e. Discussion and Action by Board for Future Criterion Selection

Dr. Oesterman stated that overutilization of acetaminophen continues to be the leading cause of emergency department toxicology admissions and requested the acetaminophen dosing criteria be re-run.

Dr. Marx felt that dosing in excessive of 2.5gm per day is too high. The FDA has not been able to come up with a consensus but has stated that a ruling will be forthcoming. Combination products have been limited to 325mg.

Dr. Shea stated that in the past, there was a significant amount of utilization greater than 4gm per day and the prescribers were lettered with little response. Pharmacies were then lettered notifying them that they were dispensing too much acetaminophen and there was a significant decrease in utilization. He asked if Medicaid can address the lower limit with the providers without the FDA's ruling of less than 4gm.

Ms. Lawrence said that the Board could do an educational letter stating that the FDA is considering this and provide a link to the FDA site. The letter can provide the number of patients that the prescriber currently has on greater than 2gm that will be impacted should the FDA lower the limit.

Keith Macdonald felt that action should not be taken until the FDA ruling is available as the FDA may rule on a limit other than 2gm. Dr. Oesterman agreed but wanted to make the prescribers aware that this will be forthcoming and be aware of the number of patients they have on large quantities of acetaminophen containing products.

Ms. Lawrence suggested an announcement on the Magellan website which all of the prescribers have access to.

Dr. England suggested in addition to educating the physicians and pharmacies, educating patients by placing "shelf talkers" (a sign or card) in pharmacies and physician offices making them aware of the acetaminophen containing products and the dosing limitation.

MOTION: David England motioned to prepare an educational document for distribution to physicians and pharmacies regarding the decrease in acetaminophen dosing.
Ms. Lawrence stated that DHCFP does not have the printing resources to provide these types of notifications. A notification can be posted on the web site and printed by providers for patient distribution and sent to all pharmacies via fax blast through the board of pharmacy. A draft notification will be prepared and presented to the Board at the next meeting.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

Dr. England stated that he commonly sees concurrent use of PPIs and H2s in his practice though there is no benefit in concomitant use of these products.

Dr. Oesterman agreed and asked if the specialty of the prescribing physician can be included to determine if they are being prescribed by gastroenterologists or another specialty.

Dr. Townsend suggested running criteria 4768 "Proton Pump Inhibitors duplication with H2 antagonists." The profile will include the different prescribers but the specialty may not be on file. A separate report will be required from another database. Once the profiles are analyzed and concomitant use is determined, the prescribers within those profiles will be identified.

MOTION: David England motioned that criteria 4768 "Proton Pump Inhibitors duplication with H2 receptor antagonists" be included in the next RetroDUR profile run.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

Dr. Oesterman asked if it is feasible to look beyond pharmacy and determine how many diabetic patients are getting their HgA1c tested and their eye and foot exams annually.

Ms. Lawrence stated that there is access to the medical reports. Lab test procedure codes are included but the results are not and podiatry is not a covered service. The diabetic report will be a comprehensive report which will require many man-hours. With the HP takeover, there will be a freeze on system changes within the next month.

vii. Presentation of Requested Report on Use of Anticonvulsants for Pain by Age Group

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Use of Anticonvulsants for Pain by Age Group

Dr. Townsend stated that at the last meeting, the Board requested that this report be re-run to include phenobarbital claims and that it be subset by age greater than or equal to 18 years and less than 18 years. The first page is a summary; the second contains detail by drug which is broken down by age group, and whether or not the recipient had an ICD-9 code for seizure disorder available within the past 12 months. She clarified that the recipients with claims are screened for the presence of an ICD-9 code for seizure disorder but patients in the group with no ICD-9 submitted could have a diagnosis of seizure disorder but the ICD-9 was not included on the claim. She reviewed the fourth page of the report which contained an analysis of recipients with no ICD-9 code for seizure disorder and concomitant use of analgesics.

Dr. England asked how this report compares with other similar size states. Is there similar utilization in other programs indicating that 75% of the time anti-seizure medications are being used for non-seizure disorder in eighteen years and older; is this the norm or exception.

Dr. Townsend stated that this report is not a "standard" report run by other states, and thus the information from other states is not available to provide a benchmark. Utilization across states in Medicaid programs indicates that these drugs are the top ten most frequently prescribed agents.

Dr. Coppola offered to obtain permission from other states to share their data and have the biostatistician run a report for a basis of comparison. Ms. Lawrence added a state with a similar population with fee-for-service and aged, blind and disabled should be used for the comparison.

Dr. Marx stated adjunctive medications should be used with pain. Neurologists and pain management specialists prescribe anticonvulsants for non-epileptic reasons. Dr. England agreed but since the percentage seemed high, he would like to see a comparison with other states. Dr. Shea said that in reviewing the report, there is a high rate of claims without a diagnosis of seizure disorder for particular agents but are justifiably used as adjunct therapy for issues other than seizure disorder which, in his opinion, is appropriate; e.g., valproate and divalproex used for behavioral issues.

MOTION: David England motioned for a report comparing the Nevada Medicaid data to similar states.
SECOND: James Marx
Dr. Marx stated that he is uncertain what the expenditure of time will yield in terms of improved drug utilization. The report presented demonstrates what is already known intuitively and he was uncertain that any further analysis will yield any tangible results.
Mr. Macdonald asked if other states have access to this and at what labor and cost for to produce it; will it be one or ten other states. Is Hewlett Packard going to have this information in the future? He felt that nothing further may be enhanced at this point.
Dr. Oesterman said that he understands the concerns but looking at the number of claims that fall within this therapeutic category, there is a potential value for this report to ensure there are not an excessive number of outliers in any one particular area.
Dr. Townsend asked for clarification as to which reports are being requested for comparison with other states; Dr. Oesterman replied the claims summary table.
AYES: Oesterman, England
NAYES: Marx, Shea, Macdonald
MOTION FAILED

viii. Presentation of Requested Report on Concomitant Use of Two Norepinephrine Serotonin Reuptake Inhibitor (NSRI) Drugs; Intervention Methods Available

a. Public Comment

No comment.

b. Discussion and Action by Board on the Concomitant Use of Two Norepinephrine Serotonin Reuptake Inhibitor (NSRI) Drugs; Intervention Methods Available

Dr. Townsend stated that this report was presented at the last meeting. At that time, the Board requested proposed intervention methods be researched and presented at this meeting. Eighteen recipients were identified with a greater than ten day overlap of different NSRIs during the reporting period (9/2009 through 9/2010). The proposed edit is a twenty-six day look back in claims history for another NSRI; if no claim, the claim adjudicates. If there is a claim within the twenty-six days, the incoming claim denies for prior authorization required (PA). At that point, the prescriber contacts the Clinical Call Center and the discussion is whether this is a transition in therapy or if the intent is to continue both drugs. The proposed edit is the most reliable mechanism to attain the results the Board has discussed versus coding the system with multiple steps which can be complex due to other existing edits on these drugs (e.g., PDL status and ICD-9 diagnostic requirements). If this is acceptable to the Board, are there any criteria for the Call Center to approve the use of two NSRIs together.

Dr. Oesterman felt that the proposed twenty-six day look back will eliminate ongoing therapeutic duplication.

Dr. Marx stated that most of the time when multiple psychotropics are used, it's by a psychiatrist. He felt that there should be a provision for an override if a psychiatrist orders two drugs within the same class.

MOTION: **James Marx motioned to implement the twenty-six day look back and deny duplicate therapy for PA required; authorization will be granted for transitional therapy; duplicate NSRIs will be authorized for ongoing therapy if ordered by a psychiatrist.**
SECOND: **David England**
Mr. Macdonald asked how frequently patients in this category might be referred back to their primary physician following a visit to a psychiatrist. Will a PA allow for duplicate therapy by a primary physician?
Dr. Oesterman replied that due to the relatively small number of patients, he felt it would not be a significant issue but wants to ensure patient safety.
Dr. England stated that there may be cases where the primary physician writes for two agents as recommended by the patient's psychiatrist. He suggested the first edit be the ICD-9 code and asked how to ensure that there is follow-up by a psychiatrist but managed and monitored by the primary care provider.
Dr. Townsend replied that type of monitoring cannot be done with a pharmacy claims data base; the system only sees the information included on the claim. Standard PAs are for a year; a six month time limit can be placed on the PA or a date of service PA can be used for a single transaction (to allow for transition from one drug to another).
Ms. Lawrence said for monitoring purposes, a ninety day or six month limit can be implemented. If the primary is writing for Cymbalta® and Savella®, for example, which of the two medications will have the six month limitation? The limitation cannot apply to all Cymbalta® claims because not all recipients are receiving concurrent therapy. She asked Magellan if a PA can go forward for one NDC having two sets of logic for a PA time period and Dr. Coppola said it can be set up based on priority.
Ms. Lawrence offered to see how other states are handling this.
Dr. Townsend reminded the Board that these agents currently require an ICD-9 for an approved diagnosis.
Dr. Shea stated that the psychiatrist Board member is not in attendance today, but he would like to have input from that specialty regarding indications for concurrent use of two NSRIs.
YEAS: **Oesterman, Marx, England, Macdonald**
NAYES: **Shea**
MOTION CARRIED

ix. Presentation of Requested Report on Early Refill Requests for Controlled Drugs: Q4 2010

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Early Refill Requests for Controlled Drugs

Dr. Townsend presented the report for fourth quarter 2010. The majority of requests for early refills were for increase in dose or dose titration followed by nursing home admissions/discharges. The number of unique pharmacies was 200; the number of unique recipients 400. There was no evidence of one particular pharmacy or recipient using this override. The tolerance level for controlled substance refills is currently 90%.

Dr. Oesterman stated that the report concurs with previous data and with no obvious trends. He recommended the report be presented every six months to ensure there are no future shifts in this pattern.

MOTION: **David England motioned that early refill requests for controlled substances be reported on a biannual basis.**

SECOND: **James Marx**
VOTES: **Unanimous**
MOTION CARRIED

x. Presentation of Requested Report on Numbers of Recipients with a Diagnosis of Diabetes who had Emergency Room Visits or Hospital Admissions

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Report on Numbers of Recipients with a Diagnosis of Diabetes who had Emergency Room Visits or Hospital Admissions

Dr. Townsend reviewed the report which compares two time periods a year apart (October 2008 through September 2009 and October 2009 through September 2010. Presented are recipients with a drug for diabetes and an emergency room (ER) visit or hospital admission where the primary coded reason for the visit/admission was diabetes. In 2010, claims count increased; total paid amount and the cost per claim increased mainly due to price increases in the products. Between October 2009 and September 2010, there were 310 recipients with at least one admission; total admissions were 493. A total of 7.1% of recipients with claims for a diabetes drug had an admission of some type. There were 511 recipients with at least one ER visit (7.4% of recipients with claims for a diabetic drug); total ER visits were 919. The admission includes overlap; i.e., an ER visit is one count; an ER visit followed by hospital admission will count as two for the same recipient. Dr Townsend compared the two years of data presented. At the last meeting, the Board noted that the drug spend for diabetic drugs has increased and asked if that resulted in saving hospitalizations and preventing ER visits. The data indicates that both the number of hospital admissions and ER visits are stable (or slightly increased). She noted that there are system limitations in extracting some of the data and will research the available data fields with the biostatistician once the criteria has been established.

Dr. Oesterman recommended establishing criteria of four or five admissions and/or ER visits per recipient. Once recipients with multiple visits or admissions have been identified, establish if they are getting test strips, labs checked regularly to help improve patient care and reduce the number of ER visits and hospital admissions.

Dr. England agreed and asked if the data indicates that the recipient has four or five visits or admissions within a year and validate that the lab testing, etc., is being done but the patient is non-compliant, what is the recourse.

Ms. Lawrence stated that with healthcare reform, DHCFP is looking into the utilization of health homes. If the data indicates that there are a significant number of patients that are non-compliant for diabetic management, information can be provided for use in health homes. She cautioned the utilization of diagnosis to find recipients. The diagnosis code in the pharmacy system is only used when required, and on the medical claims, the admitting diagnosis is not always reliable. She recommended the Board provide a list of drugs which can be utilized to identify the recipients and then apply the criteria as determined by the Board.

Dr. Oesterman suggested recipients that are utilizing insulin products could be the starting point. Dr. England agreed and two ER visits and/or two hospital admissions within a year would prompt review. Patients that are controlled shouldn't have more visits unless there is comorbidity.

Mr. Macdonald asked how to validate that the ER visits are related specifically to diabetes issues or are there other conditions for which the recipient is admitted. Dr. Townsend replied that within the claims hierarchy, there are primary and secondary diagnoses. The primary ICD-9 was used to identify diabetes related admissions or ER visits.

Dr. England stated that since the admitting diagnoses may not be reliable, the NDC for diabetes drugs should be the trigger for placing a recipient in the queue. Then determine if admission is primarily or secondarily due to diabetes and if there are two or more ER visits or admissions (or the number of

visits as determined by the American Diabetes Association). Ms. Lawrence agreed and added that once the recipients have been established, the biostatistician can produce a report which will identify other comorbidities.

Dr. Marx suggested intervening early and that one admission with a diabetes related diagnosis should be sufficient to trigger a review.

Ms. Lawrence clarified that if a recipient visits the ER and is admitted to the hospital, the ER visit does not count in the claims payment system; it becomes an admission. Based on the insulin data contained in the report, there are approximately 4,400 recipients with insulin related claims. Other criteria as discussed (one ER visit or admission, test strips, eye exams, physician visits, etc.) will be applied to determine the population to target for further analysis.

MOTION: **Keith Macdonald motioned to proceed with the report as outlined by Ms. Lawrence above.**
SECOND: **James Marx**
Dr. England stated that insulin can be the benchmark initially, and suggested that future reports be expanded to include recipients on medications for Type II diabetes. Type II diabetics not yet on insulin may experience similar complications.
Dr. Oesterman agreed.
VOTES: Unanimous
MOTION CARRIED

xi. Presentation of Requested Report on Carisoprodol (Soma) Claims

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Report on Carisoprodol (Soma) Claims

Dr. Townsend stated that this report was presented at the last meeting as informational, not as an action item. At that time, the Board expressed interest in recommending the Pharmacy and Therapeutics Committee (P&T) review the class.

Dr. Oesterman clarified that the item on the agenda should not have necessarily been isolated to carisoprodol as all of the skeletal muscle relaxants are included in the report. There is no step therapy associated with the skeletal muscle relaxants. The issues identified in the report appear to be volume of claims and the number of claims for brand name products. The paid per claim for brand name products is significant. There is concern with the misuse of carisoprodol compounds. Carisoprodol is a prodrug metabolized to meprobamate which appears to have beneficial effects and asked the Board if, in their view, carisoprodol usage should be monitored. He stated that the carisoprodol products are included on the Preferred Drug List (PDL) and suggested a recommendation for P&T Committee review to consider if they want to continue with the inclusion of all of the skeletal muscle relaxants on the PDL.

Mr. Macdonald suggested reviewing the utilization between hydrocodone and carisoprodol since there are individuals that have repeat use of both products. Dr. Townsend added that use of these two products is a very frequent combination.

Dr. Marx stated that there are no good peer review articles that show efficacy with most of the skeletal muscle relaxants and carisoprodol has a high capacity for abuse. The report indicates high use of the drug and probably a lot is inappropriate. He expressed concern regarding the relative number of other equally if not more effective skeletal muscle relaxants that are not being used.

Dr. Shea commented that if a RetroDUR profile run were to include Vicodin® and carisoprodol use, it's probable that every physician would be lettered. Multiple use of skeletal muscle relaxants has been run in the past with a low response rate from the physicians. These agents are different in their activity and some physicians prefer use of more than one.

Ms. Lawrence suggested allowing the first drug to process and apply a clinical edit for the second agent which would require a call to the Clinical Call Center. Criteria for use of a second agent would need to be developed. Dr. Coppola added that this could be in the form of a ProDUR edit for therapeutic duplication which can be accomplished systematically.

Dr. Marx stated that he feels that there is not much justification for duplicate use of two skeletal muscle relaxants even accounting for their different modes of action; interactions in that type of therapy is unpredictable. Dr. England agreed adding that there is no rationale for use of two other than for transitioning.

Dr. Townsend offered to run a report on multiple use and overlap of the skeletal muscle relaxants in order to determine if there is an issue and present for Board review.

MOTION: David England motioned that a report on multiple use and overlap of the skeletal muscle relaxant agents be presented at the next meeting.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

MOTION: Keith Macdonald motioned that the DUR Board make a recommendation to the P&T Committee to give consideration to non-prefer carisoprodol and carisoprodol compounds.
Ms. Lawrence asked for clarification if the recommendation to P&T is to non-prefer the drugs or remove them from the PDL.
Mr. Macdonald clarified that his recommendation is for consideration to non-prefer the drug.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

xii. Proposed Prior Authorization Criteria for Colcrys® (colchicine) for Prophylaxis of Gout Flares

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Clinical Prior Authorization Criteria for Colcrys® (colchicine) for Prophylaxis of Gout Flares

Dr. Townsend stated that this item is being presented to update criteria to consider the indication of prophylaxis. The manufacturer of this product has both an acute and chronic prophylactic indication. The prophylaxis dose is 0.6mg once to twice daily. Colchicine is a drug with a narrow therapeutic toxicity window associated with an important variability in tolerance amongst subjects. It's associated with significant drug interactions and adverse drug events, which although low in frequency, are potentially fatal. In terms of prophylaxis, there are few controlled trials for chronic therapy. The data in the package insert (PI) supporting prophylaxis was taken from the literature that was done with the original colchicine product. One study referenced in the PI and marketing materials was a placebo-controlled trial of forty-two patients starting allopurinol using "unapproved" colchicine 0.6mg BID. During the first three months of uric acid lowering therapy, colchicine reduced the number of flares from a mean of roughly 1.9 to 0.6; during the second three month period, it was reduced from 1 to 0. There are two xanthine oxidase inhibitors available on the market for the management of elevated serum uric acid levels in patients with gout. They can cause flares, particularly during initiation, which can be treated with NSAIDs and steroids as per acute therapy as well as colchicine. What is being proposed to be added to the existing criteria is section 1.c.
"Recipient has a diagnosis of chronic gout requiring prophylaxis and recipient has failed therapy with two xanthine oxidase inhibitors within the last 180 days or recipient has a contraindication to both xanthine oxidase inhibitors." The quantity limit for chronic gout requiring prophylaxis is 60 tablets per 30 days; length of authorization is one year.

Dr. Oesterman pointed out that in section 1.c, "xanthing" should be corrected to "xanthine".

MOTION: David England motioned to approve the revised prior authorization criteria to include 1.c and 2.b.ii.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

xiii. Proposed Prior Authorization Criteria for Pradaxa® (dabigatran etexilate)

a. Public Comment

Susan Wood, Boehringer Ingelheim, spoke in support of Pradaxa®. Pradaxa® is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. For patients with creatinine clearance (CrCl) >30, the recommended dose is 150mg twice daily, with or without food. For patients with CrCl 15-30, the recommended dose is 75 mg twice daily. Patients with a CrCl <15 or on dialysis have not been studied therefore there are no recommendations. She cited the RE-LY Trial which compared Pradaxa® 110 mg twice daily and 150 mg twice daily with open-label warfarin dosed to target INR of 2 to 3 in patients with non-valvular, persistent, paroxysmal, or permanent atrial fibrillation and additional risk factors. The primary efficacy composite endpoint was time to first occurrence of stroke, (ischemic and hemorrhagic) and systemic embolism. Relative to warfarin, Pradaxa® 150 mg twice daily significantly reduced the primary composite endpoint from 3.4% for warfarin to 2.2% for Pradaxa® 150mg with a hazard ratio of 0.65; relative risk reduction of 35%. The treatment effect was primarily a reduction in both ischemic and hemorrhagic stroke. There was a higher rate of bleeding in patients greater than 75 years of age and a higher rate of major gastrointestinal bleeding with patients on Pradaxa® 150mg versus warfarin. The rates of adverse reactions leading to treatment discontinuation were 21% for Pradaxa® 150 mg and 16% for warfarin. The most frequent adverse reactions leading to discontinuation were bleeding and gastrointestinal events. The risk of MI was numerically greater in patients receiving Pradaxa® 150 twice daily versus those that received warfarin. Pradaxa® is contraindicated in patients with active pathological bleeding and those with hypersensitivity to any of the ingredients. There is an increased risk of bleeding with concomitant medications such as antiplatelets and heparin.

b. Discussion and Action by Board on the Review of Clinical Prior authorization Criteria for Pradaxa® (dabigatran etexilate)

Dr. Townsend stated that Pradaxa® is the new competitive direct thrombin inhibitor approved for non-valvular afib to reduce the risk of stroke and systemic embolism as a combined outpoint. It's taken in a fixed dose, 150mg BID, and has a very short half-life. It's adjusted for renal function. If a dose is missed, it should be taken as soon as possible if it is greater than six hours before the next dose; the missed dose should be skipped if it cannot be taken at least 6 hours before the next scheduled dose. The dose should not be doubled to make up for a missed dose. The capsule should not be opened or broken due to a 75% increase in bioavailability. It must be dispensed in the original package due to moisture and stability issues. The bottle, once opened, is good for thirty days. In terms of efficacy, Pradaxa® was superior to warfarin with a relative risk reduction of 0.66. Based on this number, the NNT is about 169 patients with afib per year to prevent one event. In clinical trials, adverse drug events leading to discontinuation was 21% versus warfarin at 16%. GI complaints were frequent (one-third of patients). 17% experienced some type of bleeding; 3% had a major bleed. Overall, major bleeding complications were comparable between warfarin and Pradaxa®. There is a higher risk of bleeding in patients greater than 75 years of age. Precaution should be taken with medications that increase bleeding including platelet agents and chronic use of NSAIDs. Rates for MI were higher in Pradaxa® (0.74%/year) versus warfarin (0.53%/year). Not all adverse drug reactions were reported as typically seen in the PI. There is a median follow-up of two years of Pradaxa® for lifelong therapy. It has a narrow indication and there is a large potential of off-label use. The proposed PA guidelines were developed to restrict use to labeled indications and in patients with risk of stroke as defined by the pivotal study. The benefit of Pradaxa® over warfarin was most beneficial at centers with poor INR control. She reviewed the proposed criteria stating that they are consistent with the guidelines in terms of which patients with afib should be treated with these drugs.

Dr. England asked about criteria for transitioning between Pradaxa® and heparin or warfarin. Should the criteria include that the INRs are at or below 2.0 for approval? Dr. Townsend said the dosing recommendation is how to change from one drug to the other drug not two drugs at the same time. There is a potential time delay in getting the INR information back from the physician which may delay therapy. It would be up to the prescriber to start the medication at the appropriate time.

Dr. Oesterman stated that because this is a new product, he wants to ensure there are no issues inadvertently caused and requested that the criteria include that if the patient is transitioning, the INR should be less than two.

Dr. Marx expressed concern regarding the high risk of GI hemorrhage; include an edit for use with NSAIDs (non-COX 2 selective) that the patient must be on a PPI concurrently.

Dr. England suggested an announcement to physicians and pharmacists.

MOTION: David England motioned to accept the proposed criteria and to add in section 1.c. that the INR must be less than 2.0 and include in section 1.d. concurrent non-COX 2 NSAID use.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

xiv. Public Comment

Ms. Lawrence stated that the new governor has signed an executive order which places a freeze on all new regulations. This meeting was allowed because the DUR Board is governed under federal law and is an advisory board to DHCFP. DUR Board recommendations are implemented through DHCFP's regulations, Chapter 1200 of the Medicaid Services Manual. Recommendations from this meeting and the last meeting fall within the timeframe of the freeze. DHCFP is working through an exception process for pharmacy policy which may take several months.

Ms. Lawrence reminded the board members that they are not obligated to respond to public questions outside of the DUR Board meetings and to refer them to her. The Division has posted a fee-for-service pharmacy fact sheet, statistics report and the annual DUR report on their website. Board members with suggestions regarding the DHCFP or Magellan website should contact Ms. Lawrence.

xv. Date and Location of Next Meeting

The next meeting will be on April 28, 2011, at the Las Vegas Chamber of Commerce with videoconferencing to the Magellan Medicaid Administration office in Reno.

xvi. Adjourn

Dr. Oesterman adjourned the meeting at 3:49 p.m.